Response to Office Action of: 06/27/2007

Response Dated: 09/27/2007

Title: Nasal Peptide Pharmaceutical Formulation

App. No.: 10/516,613

Inventor: Paolo A. Veronesi et al.

Examiner: Maury A. Audet

Amendment(s) to the Claims

The following listing of claims replaces all prior versions and listings of claims in

the present application:

Listing of Claims:

1-18 (canceled).

19 (previously presented): The method according to claim 34, wherein said nasal

composition is in the form of reconstituted solution, and wherein said method

comprises:

preparing a first container with the nasal peptide either by dosing in the container

the corresponding weight of powder of active nasal peptide or by preparing a suitable

solution with a known concentration of the same, pouring the individually dosed volume

into the container and then lyophilizing it to yield a lyophilized powder;

preparing a second container comprising the solvent mixture for reconstitution,

resulting from adding an adequate amount of distilled water to THAM, and optionally to

methyl or/and propyl p-hydroxybenzoate, hydrochloric or citric acid and cysteine until

complete dissolution;

filtering to make the solution suitable for nasal administration; and

filling the second container with the filtrate.

20-33 (canceled).

34 (original): A method for imparting to a nasal composition the ability to reversibly

depolarize the nasal mucosa epithelial cells, and selectively enhance the permeability

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and improve the efficiency of active absorption of a pharmacologically active nasal

peptide or pharmacologically active salt thereof or pharmacologically active fragment

thereof through the nasal mucosa epithelial cells, said method comprising formulating

into a nasal composition a therapeutically effective amount of said peptide or salt or

fragment together with THAM [tris(hydroxymethyl)aminomethane], as a selective

absorbefacient, in an amount effective to selectively enhance the permeability and

improve the efficiency of active absorption of said peptide or salt or fragment through

the nasal mucosa epithelial cells, in a pharmaceutically acceptable, aqueous liquid

diluent or carrier therefor.

35 (original): A method for reversibly depolarizing the nasal mucosa epithelial cells, and

selectively enhancing the permeability and improving the efficiency of active absorption

of a pharmacologically active nasal peptide or pharmacologically active salt thereof or

pharmacologically active fragment thereof through the nasal mucosa epithelial cells,

said method comprising combining into a nasal composition and nasally administering

to a subject in need thereof a therapeutically effective amount of said peptide or salt or

fragment together with THAM [tris(hydroxymethyl)aminomethane], as a selective

absorbefacient, in an amount effective to selectively enhance the permeability and

improve the efficiency of active absorption of said peptide or salt or fragment through

the nasal mucosa epithelial cells, in a pharmaceutically acceptable, aqueous liquid

diluent or carrier therefor, formulated for nasal administration.

36 (original): The method according to Claim 34, wherein the nasal composition is

formulated to be non-isotonic.

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37 (original): The method according to Claim 34, wherein the nasal composition is

formulated to be devoid of methylcellulose, crospovidone, povidone and any similar

viscosity modifying agents.

38 (original): The method according to Claim 37, wherein the nasal composition is

formulated to be non-isotonic.

39 (original): The method according to Claim 35, wherein the nasal composition is

formulated to be non-isotonic.

40 (original): The method according to Claim 35, wherein the nasal composition is

formulated to be devoid of methylcellulose, crospovidone, povidone and any similar

viscosity modifying agents.

41 (original): The method according to Claim 40, wherein the nasal composition is

formulated to be non-isotonic.

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